

# *2015 Annual Meeting*

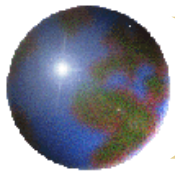
## Experiences in the Cloud

Sue-Jean Lin, Allergan

Kathleen Natriello, BMS

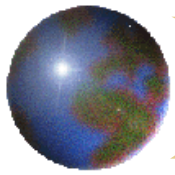
Peter Gassner, Veeva





## *A Continuation of Our Discussion...*

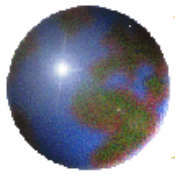
Experiences in the Cloud - explore unique challenges and opportunities associated with cloud computing with an emphasis on compliance and experience with running validated applications in the cloud....



# *Last Year's Discussion...*

1. How will Cloud adoption impact the organization risk profile?
2. Is Cloud adoption going to compromise my ability to meet regulatory mandates? How do I assure that all global regulations are met (e.g., privacy, SOX, GxP/CFR Part 11) and that effective management is in place?
3. How are security breaches handled and who is liable?
4. How do I know my company's data is protected and how do I ensure data privacy is managed?
5. What information and security policies need to be updated to accommodate Cloud adoption?
6. Do I need new skills in the organization to be effective with security and compliance challenges?
7. Who has the primary relationship with cloud providers, I.T. or end-users? Who pays for cloud services (e.g. AWS hosting of consumer facing websites, SFDC licenses)? How do we maintain flexibility/agility and positive customer experiences in the organization?
8. Challenges and risks for specific cloud services, e.g. SFDC

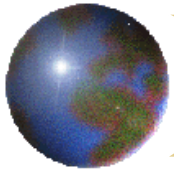




# *This Year's Discussion ...*

1. What has been the challenge of cloud adoption? What to consider when selecting cloud vendors?
2. What have I really gained from “going cloud”? What risks have escalated?
3. So I rely so much on cloud, how much can I trust the cloud provider? How to manage a business disruption if occurred?
4. What do I need to know about “cloud validation”? What is the cost?
5. What is the state of regulatory guidance? Is there a framework for cloud GxP regulatory compliance?
6. How is the life cycle management different in the cloud?
7. What components are included in the “service cost of cloud ownership”?
8. What are US and International regulators' expectations of cloud computing? What factors must be considered for US vs. international adoption?
9. Is there an opportunity for PISA / Pharma IT to engage with regulators to shape regulatory guidance?
10. What does the future cloud computing bring? What's next?

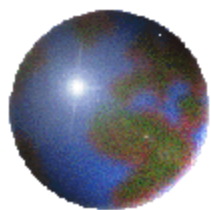




# *Agenda*

- ✚ Evaluating cloud vendors (Peter)
- ✚ PISA peer experiences
  - ✚ Validation in the cloud (Kathleen)
  - ✚ Cloud Compliance/Validation with AWS & ServiceNow (Sue-Jean)
- ✚ Cloud – the next 5 years (Peter)
- ✚ Enterprise Issues/Barriers in cloud adoption (Joint discussion)



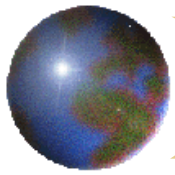


# *Evaluating Cloud Vendors*

Peter Gassner

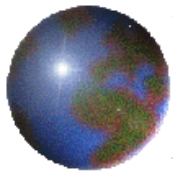
CEO at Veeva





# *Background*

1. My Background
2. Veeva as a Cloud Provider
3. Veeva as a Cloud Consumer



# *Veeva as a Cloud Consumer*

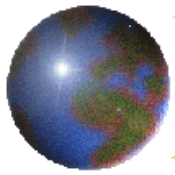
8 years old

Almost 1,000 employees

No servers on site or in sight







# *Veeva Main Cloud Solutions*

## 1. SaaS

1. Salesforce.com (SFA, Customer Support, Marketing)
2. Netsuite (ERP)
3. Gmail (mail & calendar)
4. Atlassian (software development)
5. Bamboo (HR)
6. Okta (Single signon)
7. Egnyte (file share)
8. Veeva Vault (content management)

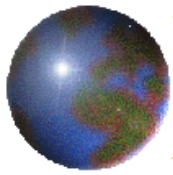
## 2. PaaS

1. Force.com (many applications)
2. Veeva Vault (content applications)

## 3. IaaS

1. Amazon, SoftLayer

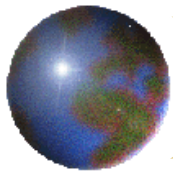




# *What Do we Look For in Cloud?*

1. IaaS, PaaS, SaaS
  1. Go with the limited set of leaders go IaaS and PaaS
  2. SaaS needs close inspection
2. Operations
  1. Separation of duties (ops, security, dev)
  2. Appropriate scale and skill
  3. Can multiple people answer questions the same way?
3. People
  1. LinkedIn is your friend. Where did people come from?
  2. Company leadership matters
4. Software capabilities
  1. Demos and Documentation
  2. Blind References
  3. Small trial where appropriate

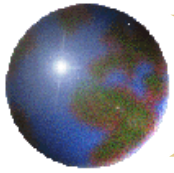




# *Example: Bamboo HR*

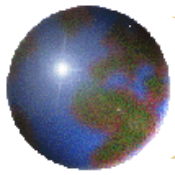
1. 3 Years ago: Veeva far too small for Workday
2. Operations
  1. Asked questions, audit over the phone.
  2. Focus on DR, security, separation of duties
  3. Eliminated 3 other providers, were about to give up
3. People
  1. Backgrounds checked out
    1. Stable team based in Utah
    2. Experienced leadership. Personal call with CEO.
4. Software capabilities
  1. Did two blind references with people we trust
  2. Evaluated integration and customization capabilities
  3. Started small





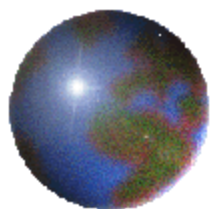
# *Example: Amazon RedShift*

1. Operations
  1. Took this for granted from Amazon
2. People
  1. Looked at backgrounds of key leaders
  2. Found out size and quality of product investment
3. Software capabilities
  1. Documentation
  2. Did two blind references with people we trust
  3. Trying it in a small way first



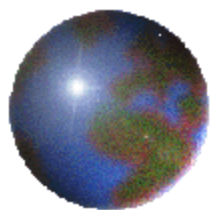
# *Your Report Card...*

1. Have you audited Veeva well?
  1. Not consistent as individual companies
  2. As a group it has helped
2. Many findings in the early years were correct and helped Veeva
  1. Operations scale and separation
  2. Quality scale and separation
  3. Process and training
3. Is it cost effective today?
  1. Not as much. Fewer findings. Minor findings.
  2. No reuse of findings across companies
  3. But small cost in the grand scheme of things and worth it

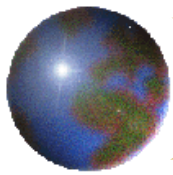


# *BMS Contribution*

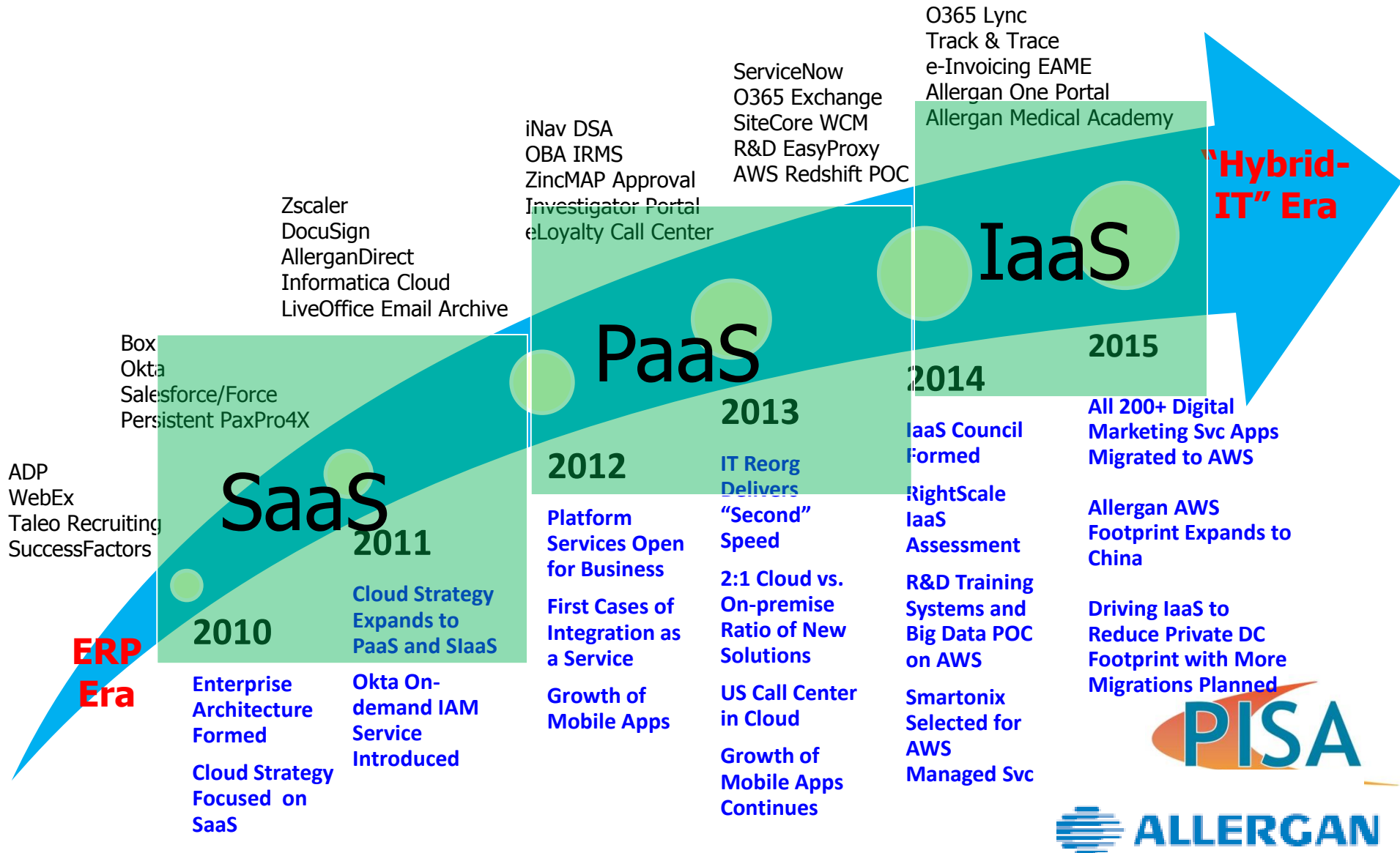
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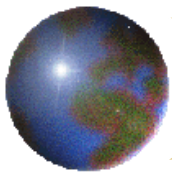
# *Allergan's Experience*



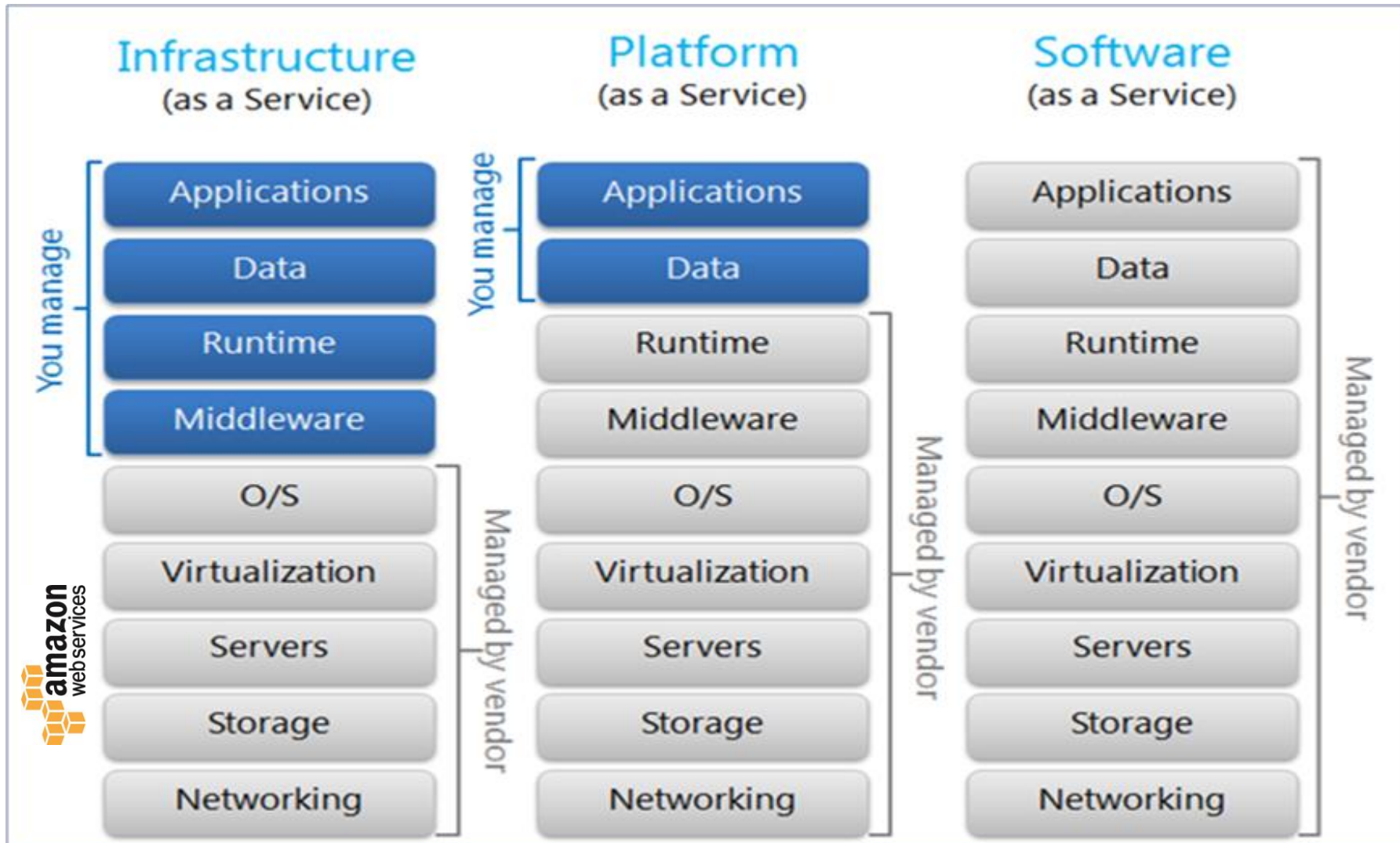
# Allergan's "Cloud Journey"

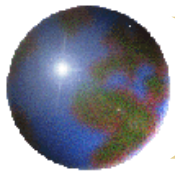






# Who's MANAGING What?

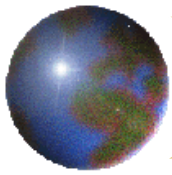




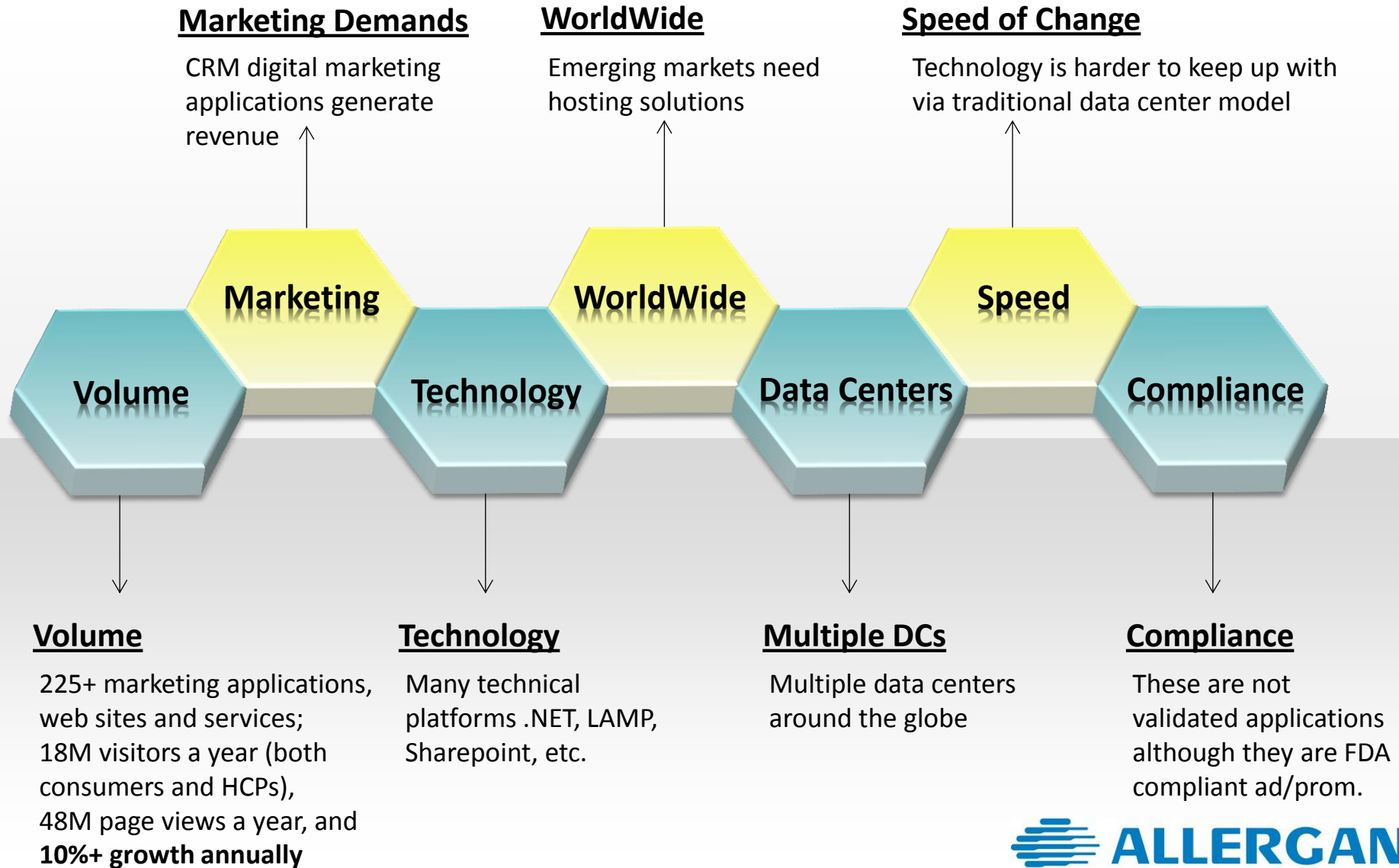
# *Perception vs. Reality?*

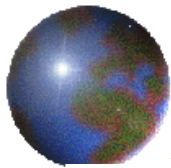
- ⊗ It's not safe, it's unproven
- ⊗ No one else in pharma does this
- ⊗ You can't touch the servers
  - ⊠ How can we have validated servers?
  - ⊠ GxP Validation and Qualification
- ⊗ We won't save money
- ⊗ Our people don't have the right skills
- ⊗ Our partners don't understand our regulatory requirement
- ⊗ We will impact our customer SLAs
- ⊗ How do we do disaster recovery?





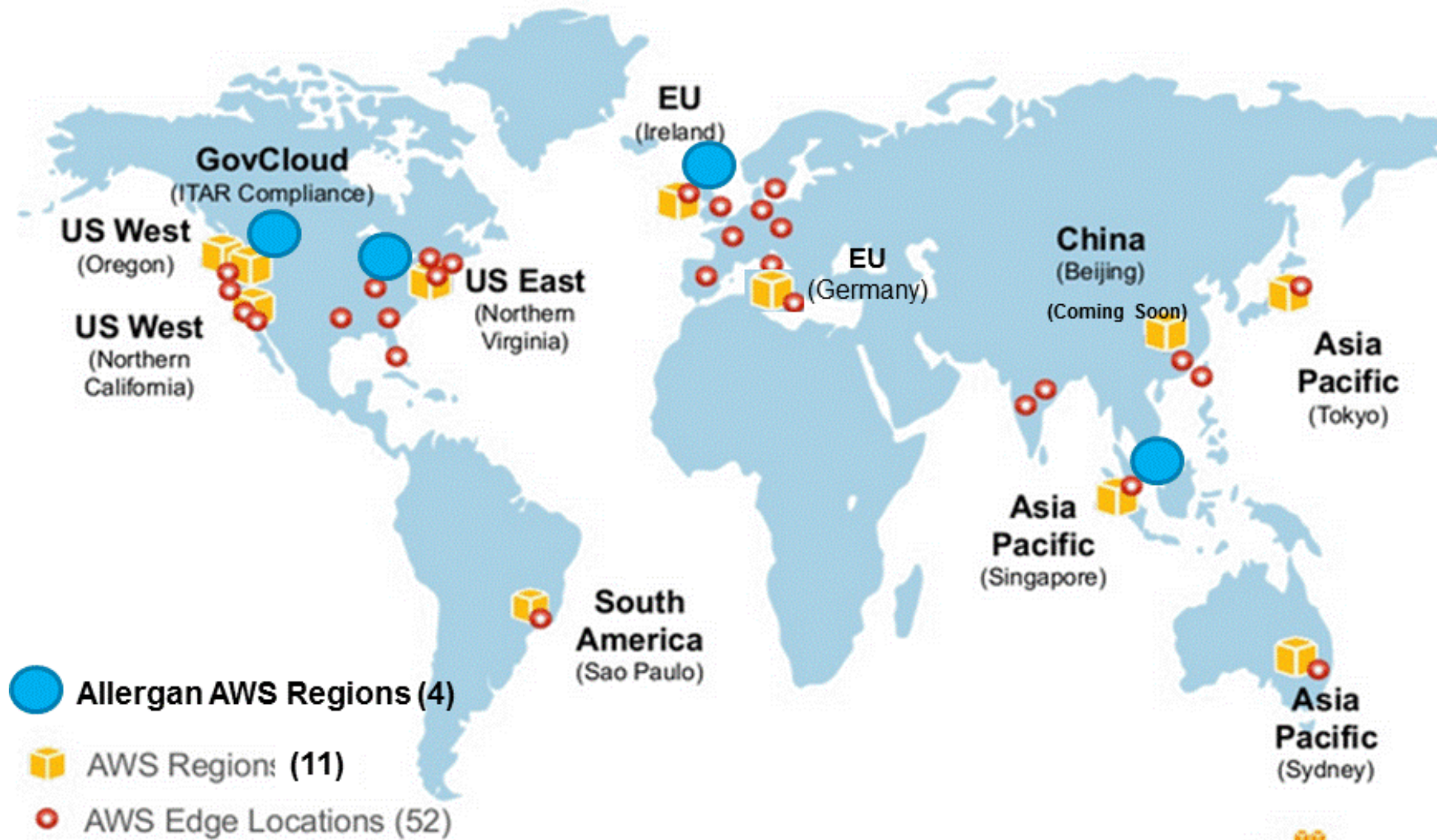
# Allergan's Digital Marketing Services Platform



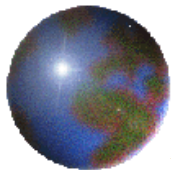


# Allergan's Digital Marketing Services Platform

## AWS Regions







# ***Risk-based IaaS Cloud Compliance***



## **Comprehensive Risk Analysis for AWS Cloud**

- Regulatory risk assessment (GxP, SOX, Privacy, Select Agent)
- Business, legal, and contractual risk assessment



## **Special Contract Addendums**

- Quality Agreements (GxP), Technology Control Plan (Select Agent)
- Security and Privacy Addendum (Data Privacy)



## **Risk-based AWS Cloud Policies & Procedures**

- IT General Controls, Infrastructure Qualification, Cloud Validation
- Security standards



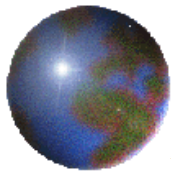
## **Cloud Vendor On-boarding Program**

- AWS Cloud Vendor Security & Compliance Assessment
- Leveraging AWS Certification (ISO 27001, FedRAMP, Safe Harbor,



## **Effective Security Controls**

- Encryption, AWS IAM, etc.
- Cloud-based Federated Identity and Access Management



# Allergan's AWS GxP Program

- ❑ AWS ISO 27001 Certification
- ❑ AWS FedRAMP Certification
- ❑ AWS CloudTrail™

- ❑ AWS ISO 9001
- ❑ AWS Quality Agreement
- ❑ AWS FDA Mock Audit Report

2013

- ❑ AGN On-Boarding of AWS
- ❑ AGN Compliance Whitepaper

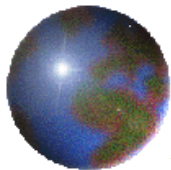
2014 - 2015

- ❑ AGN IaaS Security Standards
- ❑ AGN IaaS Encryption Policy
- ❑ AGN IaaS IT Control Policies
  - Change Management
  - Access Management
  - Backup / DR Mgmt
- ❑ AGN IaaS Qualification SOPs
  - EC2/S3/EBS/VPC/Glacier
  - Machine Images

2015+

- ❑ AGN Quality Agreement with AWS
- ❑ AGN Annual Compliance risk assessment
- ❑ AGN Automate AWS Qualification
  - SolarWind
  - QualysGuard
  - CloudTrail





# State of AWS Cloud Compliance

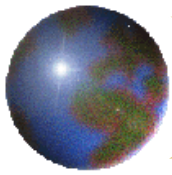
The Digital Marketing Services applications moved to AWS were not validated applications and do not require validated infrastructure.

Compliance Area	2014	2015
GxP, 21 CFR Part 11, EU Annex 11*	●	●
US Data Privacy	●	●
EU & International Data Privacy**	●	●
IT SOX 404	●	●
Select Agent Regulations***	●	●

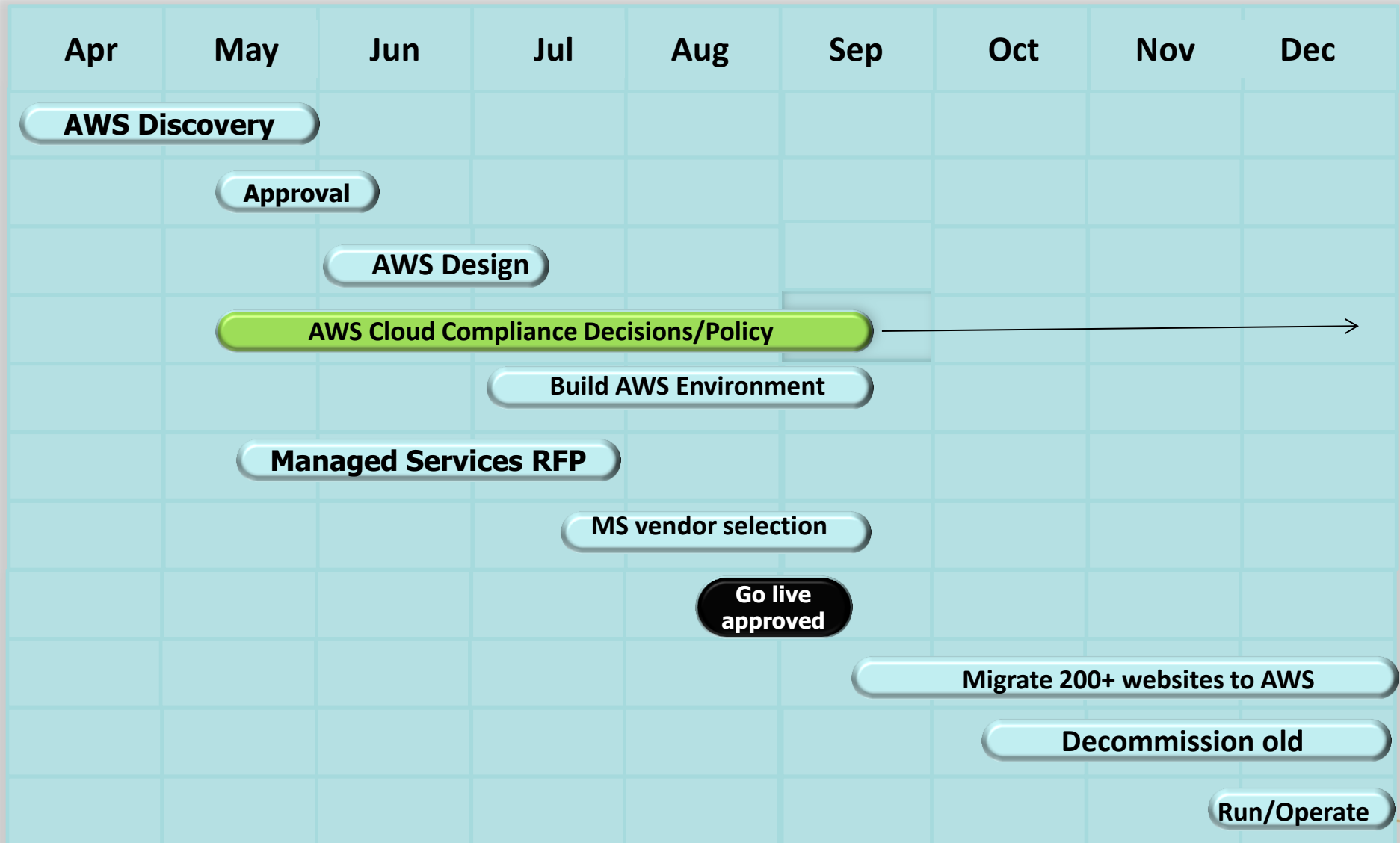
\* Allergan continues to partner with AWS to drive GxP requirements

\*\* Leveraging AWS and Allergan US-EU Safe Harbor Certification

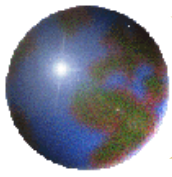
\*\*\* Leveraging U.S. Certification for AWS Cloud through FedRAMP ([cloudCIO.gov](http://cloudCIO.gov))



# How long was our journey?







# ***AWS Platform Benefits***

1 Compliance neutral; validated apps coming soon

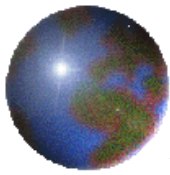
2 Scalable technical platform established which can easily accommodate company **growth**

3 Platform is **operationally efficient** to run; we can manage world-wide hosting centrally; DR is MUCH easier/cheaper.

4 **Infrastructure improvement** is seen via our increased nimbleness; hardware requirements managed in day vs. weeks

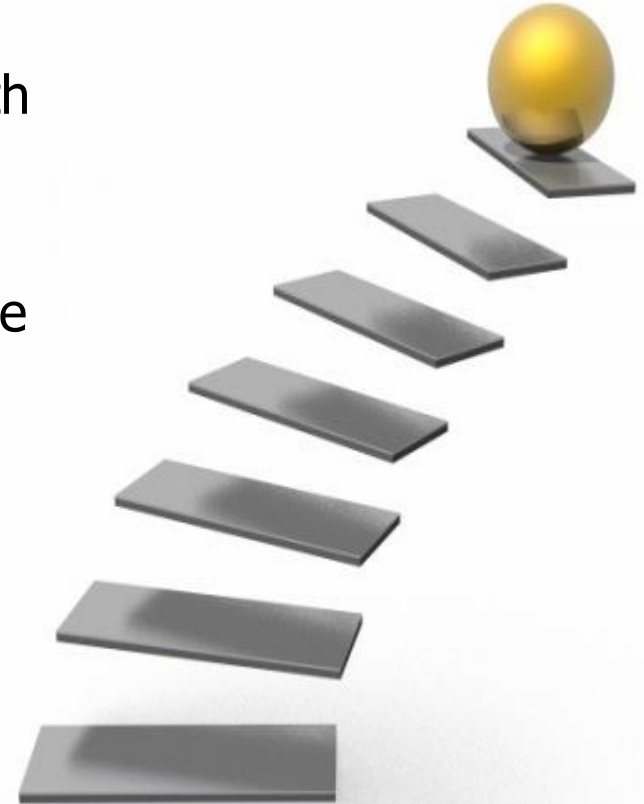
5 **Cost Savings.** Excellent data center consolidation solution, AWS pricing efficiencies continue to be impressive





## *Some Learnings ...*

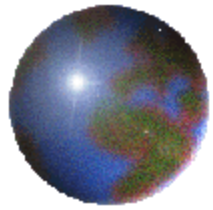
- ✚ Pick a few applications for pilot; started with Non-validated
- ✚ Pilot team members
  - ✚ Security and network team members are critical
- ✚ Utilize your technical vendors
  - ✚ Don't hesitate to lean on them
- ✚ Managed Services is evolving
  - ✚ Consider selecting one vendor for build/migration and another for run
- ✚ Embrace continuous learning
  - ✚ Expect to be uncomfortable



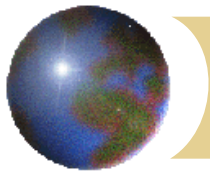
**IAAS / AWS - A HIDDEN GEM IN THE CLOUD.**



**WELL WORTH CONSIDERING.**



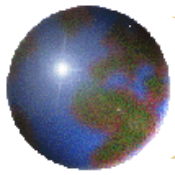
# *Allergan's ITSM ServiceNow Cloud Validation*



# *Allergan ServiceNow ITSM Validation*

- ✿ A validated ServiceNow Cloud enables IT to operate efficiently in a GxP environment
  - ✦ Eliminating all paper forms
  - ✦ Leveraging electronic signatures
  - ✦ Controlling system inventories (CMDB)
  - ✦ Simplifying system periodic review activities
  - ✦ Global electronic auditing of I.T. services
- ✿ Fully validated in < 4 months
- ✿ Validation <10% of project cost
- ✿ Passed GMP inspections and SOX audit

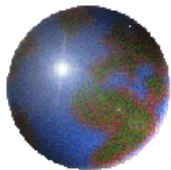




# GxP Compliance Challenges

- ✚ FDA allows GxP applications in the Cloud, but ...
- ✚ Must meet five requirements\*:
  - ✓ Risk-based validation of the Cloud application
  - ✓ Proven GxP defensible
  - ✓ Effective security controls
  - ✓ Reliable and compliant cloud provider
  - ✓ Comprehensive Cloud strategy for GxP
- ✚ Allergan currently meets or exceeds these requirements.





# *Risk-based Cloud GxP Compliance*



## **Comprehensive Risk Analysis for Cloud**

- Regulatory risk assessment (GxP, SOX, Privacy)
- Business, legal, and contractual risk assessment



## **Defined Cloud Quality Agreements**

- For IaaS, PaaS, and SaaS Cloud Service Providers
- Based on U.S. FDA 2013 Guidance and U.S. Government FedRAMP\*



## **Risk-based Cloud Validation**

- Internal policies and SOPs for Cloud Validation & Controls
- Based on U.S. FDA & EU Annex 11 requirements



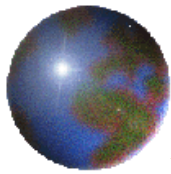
## **Cloud Vendor On-boarding Program**

- Cloud Vendor Security & Compliance Assessment
- Periodic Re-evaluation



## **Effective Security Controls**

- Encryption (in transition and at-rest) based on risks
- Cloud-based Federated Identity and Access Management



# *ServiceNow Cloud Validation Overview*

GxP Compliance Risk

## **Allergan ServiceNow Configuration**

- ☐ Risk based validation of all AGN Configuration
  - ✓ High Risk: Change, CMDB, e-Signature
  - ✓ Medium Risk: Incident, Problem, Asset, IT GRC
  - ✓ Low Risk: Knowledge, Service Mgmt.
- ☐ Re-usable test scripts for annual release updates
- ☐ Limited custom/special Java scripting

## **Allergan ServiceNow Instance**

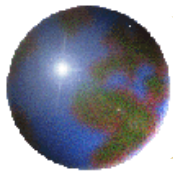
- ☐ Allergan contract with ServiceNow includes:
  - ✓ Baseline documentation for Allergan instance
  - ✓ Performance testing & configuration reviews

## **ServiceNow SaaS Cloud**

- ☐ Allergan assessed ServiceNow for
  - ✓ IT General Controls
  - ✓ Security & Privacy Controls
  - ✓ SDLC & Software Quality Assurance

## **Equinix Data Center Hosting**

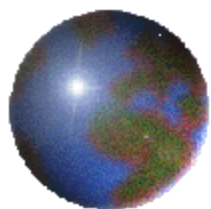
- ☐ Allergan assessed the hosting environment:
  - ✓ Equinix SSAE16 SOC 2 Report
  - ✓ ServiceNow Controls at Equinix Data Center



## *Example of Validation in ServiceNow*

ServiceNow Module	Compliance Risk	Validation Approach
Incident Management	Moderate	Full UAT
Problem Management	Moderate	Full UAT
Change Management	High	Full PQ
CMDB	High	Full PQ
Knowledge Management	Low	Abbreviated UAT
Asset Management	Low	Abbreviated UAT
IT GRC	Moderate	Full UAT



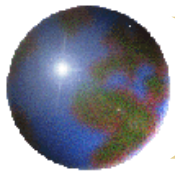


# *Clouds Ahead*

Peter Gassner

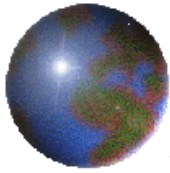
CEO at Veeva





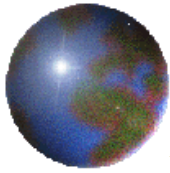
# *Cloud Trends – Last 5 Years*

1. SaaS matures
2. IaaS
3. PaaS
4. Smaller web services
5. Freemium

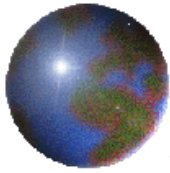


# Cloud Next 5 Years



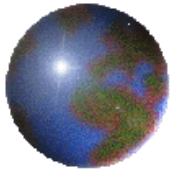


# The China Cloud



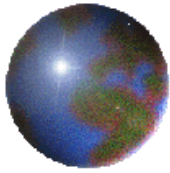
# Amazon as Linux





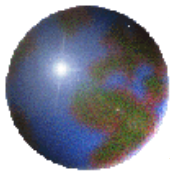
# Trust Nodes





# Industry Specific SaaS

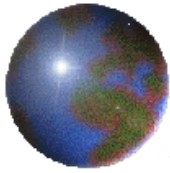




# SAP Evolves

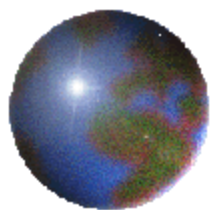






**\$1Billion and no Servers**





*Thank you!*